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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,277	03/01/1999	KENJI KAWADA	32-248P	8984

7590

06/13/2003

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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT PAPER NUMBER

1624

DATE MAILED: 06/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/214,277

Applicant(s)

KAWADA ET AL.

Examin r

Venkataraman Balasubramanian

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-- The MAILING DATE f this communicati n appears on the cover sheet with the c rrespondence address --

**Period f r Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29-37,40 and 42-58 is/are pending in the application.
- 4a) Of the above claim(s) 29-33,50 and 51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-37,40,42-49 and 52-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

Applicants' response, which included amendment to claims 37, 40, 42 and addition of new claims 57-58, filed on 3/17/2003, is made of record.

Claims 29-37, 40, 42-49, and 50-58 are in the application. Claims 29-33 and 50-51 were withdrawn from consideration as noted in the previous office action.

Claims 34-37, 40, 42-49, and 52-58 are active in the application.

In view of applicants' response, 102(b) rejection over Coates et al., made in the previous office action has been obviated. However, the following rejections made in the previous office action remain.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-37, 40, 45-49 and 52-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record. Any claim not specifically rejected is rejected as being dependent on a rejected claim. To repeat:

1. Recitation of the term "prodrug" in claims 34-37, 40, 45-49 and 52 is deemed as indefinite. Prodrugs in general and as noted in specification, are compounds, which undergo in vivo hydrolysis to parent active drugs. In that sense recitation of prodrug is acceptable. However, the definition of various R, groups include such groups, namely esters, amides, alkoxycaronyl etc. and therefore it is not clear what is the difference between these variable groups and the prodrug groups.

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This rejection is same as made in the previous office action except that the newly added claims are also rejected herein.

Applicants' argument to overcome this rejection is not persuasive for reasons of record.

As for the traversal the following apply:

Applicants assert that one trained in the art would be able to distinguish between a prodrug and the instant active compounds lacks factual support. How would one distinguish between the two? How would one know which group say an ester group is a prodrug group or not a prodrug group? How would one know given two ester groups, which of these ester groups would undergo hydrolysis in vivo to qualify as prodrug?

Hence this rejection is proper and is maintained.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 34-36, 45-49, and 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coates et al. WO 93/22397 for reasons of record.

This rejection is same as made in the previous office action except that the newly added compound claims 57-58 are also rejected herein and claim 40, which is now a pharmaceutical composition claim, is excluded.

Applicants' traversal to overcome this rejection is not persuasive.

Applicants' argument that fluorine is an electronegative atom and therefore substituting the fluorine by other groups recited in the reference will not lead to the

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desired liquid crystal property is merely a speculation. Applicants have not provided any evidence.

Furthermore, Coates et al. teaches equivalency of the said fluorine groups with other groups recited in the definition of substituents in the phenyl ring. Therefore, one trained in the art would accept Coates teaching and would be motivated to make compounds variously substituted in the aryl ring.

Hence the above rejection is proper and is maintained.

References cited in the Information Disclosure Statement (paper # 20) are made of record. In view of large number of references, prior art rejections are solely based on the earlier search and Information Disclosure Statement provide by the applicants.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

VB

V. Balasubramanian

6/12/2003

*Mukund J. Shah*

MUKUND J. SHAH

SUPERVISORY PATENT EXAMINER

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